NEBRASKA BOARD OF PHARMACY

MEETING MINUTES July 13, 2015

ROLL CALL

Jennifer King, R.P., Chair, called the meeting of the Board of Pharmacy to order at 8:36 a.m. in the Lighthouse Room of the Country Inn & Suites, located at 5353 North 27th Street, Lincoln, Nebraska. The agenda was provided to Board members, posted on a public bulletin board in the Nebraska State Office Building, posted on the Department's website, and e-mailed to the "interested parties" list prior to the meeting. The following Board members answered roll call:

Jennifer King, R.P., Chair Michael Losee, Secretary Kenneth Saunders, R.P. Robert Marshall, R.P.

Absent: Patricia Gollner, R.P., Vice-Chair

A quorum was present and the meeting convened.

Also present were: Julie Agena, Assistant Attorney General; Mike Rueb, R.P., Pharmacy Inspector; Dean Willson, Jr., R.P., Pharmacy Inspector; Kathie Lueke, Program Manager; Vonda Apking, Health Licensing Coordinator; Kevin Griess, Department Legal; Jeff Newman, Investigator; Kathleen Krueger, Investigator; Russ Fosler; Investigator; and Peggy Persell, Program Manager, Investigations Unit.

King announced that there is a copy of all the public documents being reviewed at this meeting available in the meeting room pursuant to the Open Meetings Act.

Marshall commented that he was disappointed that discussion regarding the Food and Drug Administration (FDA) Inspection of compounding pharmacies was not on the agenda. Marshall requested that there be discussion regarding FDA Inspections at an upcoming meeting.

REVIEW OF AGENDA

Adoption of Agenda

Marshall moved, seconded by Losee, to approve the agenda as presented with the Chair having the authority to rearrange agenda items as needed. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: none. Absent: Gollner. Motion carried.

Shannon Peter, RP, and John Jacobsen, MD, from Think Whole Person Healthcare provided the Board with an overview of their healthcare model. The Board thanked them for sharing information about their healthcare model.

Additions, Modification, Reordering

The Board requested that the following applications be removed from the consent agenda:

Carl Roney – Pharmacy Technician application
Erica Manns – Pharmacy Technician application
Lori Fisher – Pharmacy Technician application
Miya Hicks – Pharmacy Technician application
Nicole Ravenelle – Pharmacy Technician application
Tarah Otterstad – Pharmacy Technician application
Eric Mjeldheim – Pharmacy Technician reinstatement application
Specialty Veterinary Pharmacy – Mail Service Pharmacy application
BET Pharm, LLC – Mail Service Pharmacy renewal application
Wickliffe Pharmaceuticals – Mail Service Pharmacy renewal application

Adoption of Consent Agenda

Marshall moved, seconded by Saunders, to approve the consent agenda as amended. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: none. Absent: Gollner. Motion carried.

INVESTIGATIONAL REPORTS, DISCIPLINARY REPORTS, CONTROLLED SUBSTANCES AUDIT REPORTS & APPLICATION REVIEW - CLOSED SESSION

Marshall moved, seconded by Saunders, to close the session at 8:47 a.m. to review investigational reports, disciplinary reports, controlled substances audit reports and applications. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: none. Absent: Gollner. Motion carried.

Griess left the meeting at 8:47 a.m.

King recused herself from the meeting at 8:52 a.m.

King returned to the meeting at 8:54 a.m.

Griess rejoined the meeting at 9:04 a.m.

Marshall moved, seconded by Losee, to open the session at 10:58 a.m. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: none. Absent: Gollner. Motion carried.

APPROVAL OF MINUTES

May 11, 2015

Page 1: No changes.

Page 2: Under APPROVAL OF MINUTES March 9, 2015, correct the word "role" to "roll".

Page 3: No changes.

Page 4: Under <u>Board Certification of Pharmacy Technician</u>, delete the words "that the interested parties noted".

Page 5: Under <u>Annual Meeting – May 16-19, 2015 – New Orleans, LA – Voting Delegate and Travel Grant Information</u>, Marshall suggested adding that King was the voting delegate and Saunders was the alternate voting delegate.

Marshall moved, seconded by Losee, to approve the May 11, 2015 minutes as corrected. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

BOARD RECOMMENDATIONS ON APPLICATIONS FOR LICENSURE AND REGISTRATION

Pharmacy Technician Application(s)

Marshall moved, seconded by Saunders, to recommend issuing a pharmacy technician registration to Carl Roney. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Saunders moved, seconded by Marshall, to recommend issuing a pharmacy technician registration to Erica Manns. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Marshall moved, seconded by Losee, to recommend postponing action on the pharmacy technician registration of Lori Fisher for additional information. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Marshall moved, seconded by Losee, to recommend a one year probationary registration to Miya Hicks. The basis for the probationary registration is multiple alcohol related convictions. The probationary terms and conditions should include but not limited to quarterly employer reports and following Licensee Assistance Program (LAP) recommendations. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Losee moved, seconded by Saunders, to recommend postponing action on the pharmacy technician registration of Nicole Ravenelle for additional information. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Marshall moved, seconded by Losee, to recommend a three year probationary registration to Tarah Otterstad. The basis for the probationary registration is prior alcohol related issues. The probationary terms and conditions should include but not limited to body fluid screens, quarterly employer reports and following treatment recommendations. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Pharmacy Technician Reinstatement Application(s)

Marshall moved, seconded by Losee, to postpone action on the pharmacy technician reinstatement application of Eric Mjeldheim for additional information. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Pharmacist Application(s)

Marshall moved, seconded by Losee, to recommend a two year probationary license to Jessica DiLeo. The basis for the probationary license is current disciplinary action in Florida. The probationary terms and conditions should be similar to those taken by the Florida Board of Pharmacy. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Mail Service Pharmacy Application(s)

Marshall moved, seconded by Saunders, to postpone action on the mail service pharmacy application of Specialty Veterinary Pharmacy for additional information. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Mail Service Pharmacy Renewal Application(s)

Marshall moved, seconded by Losee, to recommend a one year probationary license for the mail service pharmacy renewal application of BET Pharm, LLC. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Saunders moved, seconded by Losee, to postpone action on the mail service pharmacy renewal application of Wickliffe Pharmaceuticals for additional information. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

REVIEW OF PHARMACEUTICAL CARE AGREEMENTS - CONSENT

REQUEST TO USE MORE THAN TWO PHARMACY TECHNICIANS PER PHARMACIST TO PARTICIPATE IN A SCIENTIFIC STUDY

Jerome Wohleb, RP, from Bryan Health, presented a request to use more the two pharmacy technicians per pharmacist to participate in a scientific study. Marshall commented that Dr. Wohleb should submit a research model explaining what will be tested, who will be involved, and how long the study will last. Dr. Wohleb agreed and the Board can review the document via e-mail ballot. The Board thanked Dr. Wohleb for providing background on his request.

PATIENT SAFETY & MEDICATION ERROR PREVENTION FOR PHARMACY ONLINE COURSE

Marshall moved, seconded by Saunders, to approve the use of this course in disciplinary cases. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

FDA DRAFT GUIDELINES - COMPOUNDING OF ANIMAL DRUGS FROM BULK SUBSTANCES

The Board acknowledged the draft guidelines but did not discuss this item.

FEDERAL TRADE COMMISSION VS. NORTH CAROLINA DENTAL BOARD SUPREME COURT OPINION – HOW DOES THIS OPINION AFFECT NEBRASKA BOARDS?

The Department explained in their memo to Nebraska Boards that it would be prudent for boards to examine the process they follow when deciding whether to issue a cease-and-desist order. In the future, if a board is presented with an allegation of unauthorized practice, the Department recommends that the board consult closely with its legal counsel to determine the most appropriate manner in which to proceed. Griess explained that the Department will not be issuing Cease and Desist letters. The Attorney General's office will be looking at each case individually to determine whether a Cease and Desist letter is warranted and does not go against the Supreme Court opinion.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY (NABP) ISSUES

Report from Annual Meeting - May 16-19, 2015 - New Orleans, LA

Marshall provided a written report to the Board regarding the NABP Annual Meeting.

District V Meeting - August 6-8, 2015 - Fargo, ND

Staff has submitted travel authorization requests for Gollner and Losee to attend this meeting. Staff will notify them as soon as approval is received.

2016 District V Meeting Planning

Marshall commented that the hotel is finalized. The Meeting will be held on August 4-6, 2016. Marshall and a few others are looking for continuing education speakers. Marshall provided Losee with Lincoln, Nebraska brochures to hand out at the 2015 District V meeting.

IMPLEMENTATION OF 2015 LEGISLATION

The subcommittee has been reviewing LB37 and determining what changes need to be made to the regulations. Staff had made changes based on the subcommittee and presented the regulations to the Board.

King is working on a response for the Anticipatory Compounding question from the May Board meeting.

REGULATIONS DEVELOPMENT

175 NAC 8 - Pharmacy Licensure

Joni Cover, Nebraska Pharmacists Association (NPA), requested that inspection standards be put back into the regulations.

172 NAC 128 - Pharmacy Personnel Licensure

Hospodka mentioned that under continued competency, continuing education is currently the only thing acceptable. The Board suggested looking at other acceptable measures of continued competency such as board certification and job shadowing.

Lueke mentioned that the subcommittee may have to meet two more times to address some of the issues mentioned.

EMERGENCY ROOM DOSING OF CONTROLLED SUBSTANCES IN CRITICAL ACCESS HOSPITALS

Kevin Borcher, RP, provided background regarding emergency room dosing. There is some concern that with the passing of LB37 that this may not be allowed. Griess commented that the statute language that Dr. Raymond quoted in his Declaratory Order is not changing substantially but the statute number is changing. The Declaratory Order is still usable, based on Nebraska statutes and language in the Code of Federal Regulations (CFR) 1301.22(c). There was a suggestion to clarify this in regulation. Department staff will write a response and forward to the NPA.

ADJOURNMENT

Marshall moved, seconded by Saunders, to adjourn the meeting at 1:14 pm. Voting aye: King, Losee, Marshall, and Saunders. Voting nay: None. Absent: Gollner. Motion carried.

Respectfully submitted,

(signature on file with the Department)

Michael Losee, Secretary Board of Pharmacy